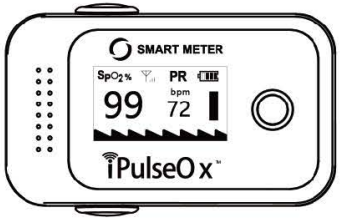
iPulseOx™

# User Manual

**Pulse Oximeter**

***SMPO1000-US***




*Manufactured for Smart Meter Corporation*
*201 E. Kennedy Blvd.*
*Tampa, Florida 33602*

**Release date: 12/01/2021 Version: 1.0**

## Product Description

A Pulse Oximeter is an important and common device used to check oxygen saturation ($SpO_2$) and pulse rate (PR). It is a small, compact, simple, reliable and durable physiological monitoring device. This device contains the mainboard, OLED display and dry batteries.

## Intended Use

The pulse oximeter is a reusable device， and is intended for intermittent checks of oxygen saturation and pulse rate of adults at home or in a clinical environment. This medical device is not intended for continuous monitoring.

## Applicable people and scope

The pulse oximeter is intended for monitoring adults. It may be used at home or in clinic settings.

## Contraindications

The pulse oximeter should not be used to monitor children. It is not suitable for use on injured skin tissue.

## Safety Information

- **Read Instructions for use prior to using your iPulseOx.**
- **The pulse oximeter is only meant to assess patients' physiological conditions.**
- **EXPLOSION HAZARD: Do not use the pulse oximeter in the presence of flammable anesthetics, explosive substances, vapors or liquids.**
- **Modification of the pulse oximeter is not recommended. Any product maintenance should be done by manufacturer-approved, professional maintenance personnel.**
- **Please shut off the power before cleaning the pulse oximeter. Disinfecting the pulse oximeter via high-pressure and high-temperature methods is prohibited. Any cleaning agents/disinfectants other than recommended ones listed in the operation manual are not recommended for use.**
- **The pulse oximeter is not waterproof. Keep its surface dry and clean.**
- **Avoid any pressure, jostling, strong vibrations, or other potential mechanical damage. Hold it carefully and lightly. If it is not in use, the pulse oximeter should be appropriately stored.**
- **Use AAA alkaline batteries.**
- **When possible keep the pulse oximeter away from any radio receivers when in use.**

## Product Feature

1. Simple and convenient operation with one button.
2. Compact, lightweight, and convenient to carry.
3. Battery indicator on screen.
4. Will automatically turn off after 10 seconds when there's no signal.
5. Device data can be record in an EMR via cellular communication.

## Display Introduction

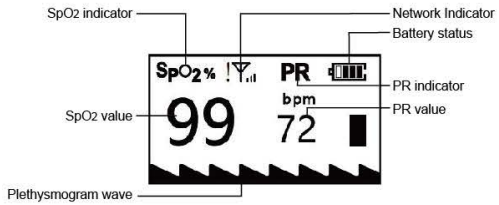



**Figure 1**

## Battery Installation

1. Open the battery compartment as shown in **figure 2.**
2. Install batteries into the slots according to the "+" and "-" symbols as shown in **Figure 3.** Cover the lid onto the battery compartment and push it upwards to make it close.

- **The positive and negative ends of batteries must be installed correctly, otherwise the device will not work.**
- **When installing or removing batteries, please follow the correct procedure, to avoid battery compartment may be damaged.**

**Figure 2**

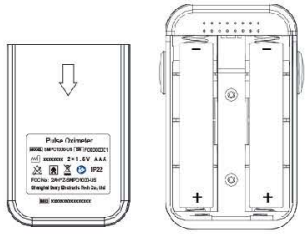


**Figure 3**

## Lanyard Installation

1. Thread the thinner end of the lanyard through the lanyard hole. The position of the lanyard hole is shown in **Figure 4.** (Notice: the lanyard hole is on both sides.)
2. Thread the thicker end of the lanyard through the thinner end of the lanyard. Then, pull the thicker end of the lanyard until it's tight.

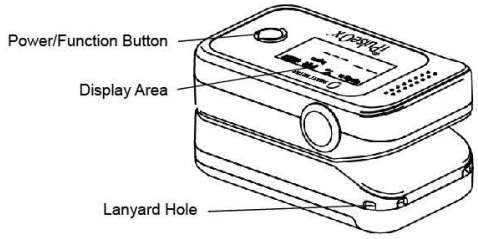



**Figure 4**

## Directions for use

1. After properly installing two AAA batteries, press lid as shown in the **Figure 5** and open the clip. Position finger into the rubber cushions of the clip, make sure the finger is in the right position as shown in **Figure 5,** and then release the clip to close over the finger.
2. Press the white button and turn on the device. Wait for a moment, the $SpO_2$ value and PR value will be displayed on the OLED screen after wave and measured values are stable, as shown in **Figure 6.**

- **Be sure to place the patient's finger inside the product in the correct orientation. The LED part of the sensor should be at the backside of the patient hand. Be sure to insert the finger deep enough into the sensor so that the fingernail is opposite to the light emitted from the sensor.**
- **Don't move the finger and remain motionless during the process.**
- **Data update period is less than 30 seconds.**

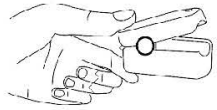


**Figure 5**


**Figure 6**

## NOTE:

- **Check the pulse oximeter for damage before use. If it's damaged, don't use it.**
- **Don't put the pulse oximeter on extremities with arterial catheter or venous syringe.**
- **Don't perform $SpO_2$ and NIBP measurements on the same arm simultaneously.**
- **Obstruction of blood flow during NIBP measurements may adversely affect the reading of the $SpO_2$ value.**
- **Don't use the pulse oximeter to measure patients whose pulse rates are lower than 30bpm (this may cause incorrect results).**
- **The well perfusion of measuring instrument should fully cover the test window of the sensor. Clean and dry the measurement part before storing the pulse oximeter.**
- **Cover the sensor with opaque material under strong light. Otherwise, the light can cause inaccurate measurements.**
- **Make sure that there is no contamination or scarring on the tested finger. Otherwise, the results may be incorrect.**
- **The device is intended for single patient use.**
- **Incorrect placement of the sensor may affect the accuracy of the measurements. The same horizontal position parallel with heart should be chosen to achieve the best measurements.**
- **The highest temperature of usage shouldn't exceed 41℃ (105 Farenheit).**

**Factors affecting measurement accuracy:**

- **The measurements depend on absorption of special wavelength ray by oxidized hemoglobin and deoxyhemoglobin. The concentration of non-functional hemoglobin may affect the accuracy of the measurement.**
- **Shock, anemia, hypothermia, and vasoconstrictive drugs may decrease arterial blood flow to an unmeasurable level.**
- **Pigments or deep colors (i.e nail polish, artificial nails, dyes, or pigmented cream) may cause inaccurate measurements.**

## Data Communication Function Description

**a.** Once the data has been displayed on the screen, the cellular data transfer will begin automatically. Uploading will appear on the screen (as shown in **Figure** 7).

**b.** The $SPO_2$ reading, and the PR will be uploaded in the patient record associated with the device serial number. Once the data has been transferred the screen will display a message "Goodbye". (as shown in **Figure 10**).

**c.** The device will automatically be powered off after a few seconds.

**d.** When the received signal is inadequacy, " ▬▬ ▬▬ " will be displayed on the screen. (as shown in **Figure 9**)

**e.** Once the data has been displayed on the screen, pressing the "POWER/ FUNCTION" button one time, the display direction will be rotated. (as shown in **Finger 8**)

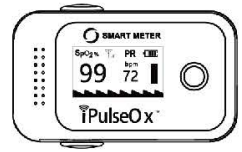



**Figure 7**

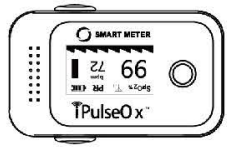



**Figure 8**

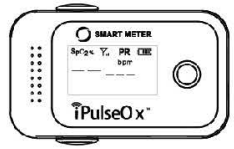



**Figure 9**


**Figure 10**

## Cleaning and Disinfection

- **Do not immerse the device or any relevant accessories in water or disinfectant.**

1. Clean the product with cotton or soft cloth lightly moistened with water.
2. After cleaning, dry with a soft cloth or allow the device to dry naturally.

**Disinfection**

The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde (2%) solution disinfectants.

1. Clean the product as instructed above.
2. Disinfect the product with cotton or soft cloth moistened with one of the recommended disinfectants.
3. After disinfection, wipe off the device with a soft cloth moistened with water.
4. Leave the device to dry naturally.

## Packing List

| **The standard configuration** | |
|---|---|
| Pulse Oximeter | 1pc |
| Zipper case | 1pc |
| Lanyard | 1pc |
| The operation manual | 1pc |
| AAA Alkaline batteries | 2 pcs |

**Expected service life:** 3 years

## Technical Specifications

**1. Display mode:** OLED

**2. $SpO_2$:**

Measurement range: 0~100%

Accuracy: ±3% (70%~100%)

**3. Pulse Rate:**

Measurement range: 25~250bpm

Accuracy: ±2bpm

- **Pulse Rate accuracy has passed the verification and comparison with $SpO_2$ simulator.**

**4. Low perfusion:**

Range: 0.5%~20%

SpO2 accuracy: ±3% (70%~100%)

PR accuracy: 25~250bpm, ±2bpm

**5. Electrical specifications:**

Working voltage: D.C.2.2 V~D.C.3.4V

Battery Type: Two 1.5V AAA alkaline batteries

Power consumption: smaller than 50mA

**6. Product specifications:**

Size: 58 (H) × 34 (W) × 30(D) mm

Weight: 50g (include two AAA batteries)

**7. Environment requirements:**

**Temperature:**

Operation: +5~+40°C

Transport and storage: -10~+50°C

**Humidity:**

Operation: 15%~80%(noncondensing)

Transport and storage: 10%~90%(noncondensing)

**Atmospheric pressure:**

Operation: 860hPa~1060hPa

Transport and storage: 700hPa~1060hPa

**NOTE:**

Wavelength: 666nm/905nm

Output power: <0.1mW

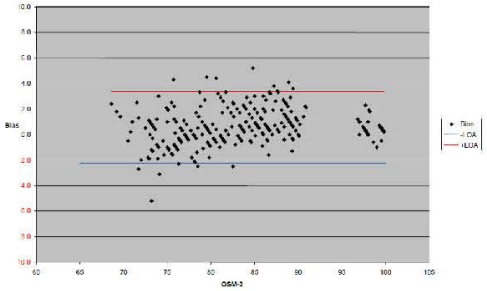
## Arms Specifications

1. $SpO_2$ Arms:

| SpO2 Range | Arms Specification |
|---|---|
| 70% - 80% | 1.65 |
| 80% - 90% | 1.22 |
| 90% - 100% | 1.11 |

2. Clinical Data Graphical Plot:

| Hemoximeter Range | 60-80 | 80-100 | 60-100 | 70-100 | 60-70 | 70-80 | 80-90 | 90-100 |
|---|---|---|---|---|---|---|---|---|
| Mean | 0.27 | 0.74 | 0.58 | 0.57 | 0.90 | 0.25 | 1.00 | 0.12 |
| Count | 102 | 185 | 287 | 284 | 3 | 99 | 131 | 54 |
| Missing Data | 0 | 2 | 2 | 2 | 0 | 0 | 0 | 2 |
| Standard Deviation | 1.64 | 1.25 | 1.42 | 1.42 | 1.23 | 1.65 | 1.22 | 1.11 |
| Standard Error | 0.16 | 0.09 | 0.08 | 0.08 | 0.71 | 0.17 | 0.11 | 0.15 |
| 95% Confidence Interval | 0.32 | 0.18 | 0.16 | 0.17 | 1.39 | 0.33 | 0.21 | 0.30 |
| Upper LOA | 3.55 | 3.22 | 3.38 | 3.38 | N/A | 3.55 | 3.42 | 2.29 |
| Lower LOA | -3.01 | -1.73 | -2.23 | -2.24 | N/A | -3.05 | -1.42 | -2.05 |
| Maximum | 4.50 | 5.20 | 5.20 | 5.20 | 1.80 | 4.50 | 5.20 | 2.40 |
| Minimum | -5.20 | -3.10 | -5.20 | -5.20 | -0.50 | -5.20 | -1.60 | -3.10 |
| Root Mean Square | 1.66 | 1.45 | 1.53 | 1.53 | 1.35 | 1.67 | 1.57 | 1.11 |




## Troubleshooting

| Trouble | Possible reason | solution |
|---|---|---|
| The $SpO_2$ and PR can't be displayed normally and the value disappeared. | 1. The finger is not properly positioned.<br>2. The patient's $SpO_2$ is too low to be detected. | 1. Please try again.<br>2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right. |
| The $SpO_2$ and PR display unstable. | 1. The finger is not placed inside enough.<br>2. The finger is shaking or the testee is moving. | 1. Place the finger properly and try again.<br>2. Relax |
| The device can't be powered on. | 1. The batteries are drained or almost drained.<br>2. The installation of batteries is not correct.<br>3. The device's malfunction. | 1. Change batteries.<br>2. Reinstall batteries.<br>3. Call Customer Service at 1-844-445-8267 |
| The screen is suddenly off. | 1. The product is automatically powered off when no signal is detected longer than 10 seconds.<br>2. Power of the batteries is exhausted. | 1. Normal.<br>2. Replace the batteries. |

## Symbol Meaning

| Symbol | Meaning |
|---|---|
|  | "CAUTIOUS"! Please refer to the operation manual. |
|  | Type **BF** Equipment. |
|  | The product does not contain alarm function. |
|  | When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. |
|  | Information of manufacture, including name and address. |
|  | Date of manufacture. |
| SN | Serial Number. |
| LOT | Batch Code. |
| REF | Type Number. |
| IP22 | Degrees of protection provided by enclosure. |

**Manufactured for Smart Meter Corporation by:**

**Shanghai Berry Electronic Tech Co., Ltd.**

Unit 104, 1st Floor, 7th Building, No.1188 Lianhang Road,

Minhang District, Shanghai, China 201112

TEL: +86-21-5853 1958 FAX: +86-21-5853 0420

WEB: www.shberrymed.com

**If you need additional information, please contact customer service at 1-844-445-8267.**

## Appendix A EMC Declaration

**Guidance and manufacturer's declaration - electromagnetic emissions - for all EQUIPMENT and SYSTEMS**

| Guidance and manufacturer's declaration - electromagnetic emission | | |
|---|---|---|
| This Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of this Pulse Oximeter should assure that it is used in such an environment. | | |
| **Emission Test** | **Compliance** | **Electromagnetic Environment-Guidance** |
| RF emissions CISPR 11 | Group 1 | This Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR11 | Class B | This Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes. |

**Guidance and manufacturer's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS**

| Guidance and manufacturer's declaration-electromagnetic immunity | | | |
|---|---|---|---|
| This Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of this Pulse Oximeter should assure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment - Guidance** |
| ELECTROSTATIC DISCHARGE [a] IEC 61000-4-2 | ±8 KV contact<br>±2 KV, ±4 KV, ±8 KV, ±15 KV air | ±8 KV contact<br>±2 KV, ±4 KV, ±8 KV, ±15 KV air | Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. |
| RATED power frequency magnetic fields [b] [c] IEC 61000-4-8 | 30A/m [d]<br>50 Hz or 60 Hz | 30A/m [d] | Mains power quality should be that of a typical commercial or hospital environment. |

[a] Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

[b] Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

[c] During the test, the ME EQUIPMENT or ME SYSTEMS may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1).

[d] This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEMS and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEMS will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

**Guidance and manufacturer's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS that are not LIFE - SUPPORTING**

| Guidance and manufacturer's declaration - electromagnetic immunity | | |
|---|---|---|
| This Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment. | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** |
| Conducted disturbances included by RF fields [a] IEC 61000-4-6 | 3 V [b]<br>0.15 MHz - 80 MHz<br>6 V [b] in ISM and amateur radio bands between 0.15 MHz and 80 MHz<br>80% AM at 1 kHz | 3 V [b]<br>6 V [b] |
| Radiated RF EM fields [c] IEC 61000-4-3 | 10 V/m [b]<br>80 MHz – 2.7 GHz [d]<br>80% AM at 1 kHz [e] | 10 V/m [b] |

[a] The following apply:
- All PATIENT-COUPLED cables shall be tested, either individually or bundled
- PATIENT-COUPLED cables shall be tested, using a current clamp unless a current clamp is not suitable. In cases where a current clamp is not suitable, an EM clamp shall be used.
- No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.
- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.
- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

[b] Before modulation is applied

[c] The interface between the PATIENT physiological simulation, if used, and the ME EQUIPMENT or ME EQUIPMENT shall be located within 0, 1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT of ME SYSTEM.

[d] ME EQUIPMENT and ME SYSTEM that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

[e] Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

**Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment**

| Test frequency (MHz) | Band [a] (MHz) | Service [a] | Modulation [b] | Maximum power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
|---|---|---|---|---|---|---|
| 385 | 380—390 | TETRA 400 | Pulse modulation [b] 18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430—470 | GMRS 460, FRS 460 | FM [c] ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710<br>745<br>780 | 704—787 | LTE Band 13, 17 | Pulse modulation [b] 217 Hz | 0.2 | 0.3 | 9 |
| 810<br>870<br>930 | 800—960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation [b] 18 Hz | 2 | 0.3 | 28 |
| 1720<br>1845<br>1970 | 1700—1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation [b] 217 Hz | 2 | 0.3 | 28 |
| 2450 | 2400—2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation [b] 217 Hz | 2 | 0.3 | 28 |
| 5240<br>5500<br>5785 | 5100—5800 | WLAN 802.11 a/n | Pulse modulation [b] 217 Hz | 0.2 | 0.3 | 9 |

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.